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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,077	09/30/2003	Mark S. Ortiz	END5100.0515145	9132

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

N_i

Office Action Summary	Application No. 10/675,077	Applicant(s) ORTIZ, MARK S.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,8-13,15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12,13,15 and 17 is/are allowed.
- 6) ☒ Claim(s) 1,5,8-11 and 18 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/21/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 10 filed 9/7/06, with respect to claims 12, 13, 15 and 17 have been fully considered and are persuasive. The rejection of 12, 13, 15 and 17 has been withdrawn.

Applicant's arguments filed 9/7/06 with respect to claims 1 and 18 have been fully considered but they are not persuasive. Applicant argues that Huebsch is not capable of actuating each actuating member individually and thus incapable of positioning the device by actuating one ring and then actuating the second. Examiner respectfully disagrees. Column 5, proximate lines 55-65 of Huebsch describes wherein each member may be actuated individually, and further, as seen in figure 18, there are two separate actuators (312 and 310) that may be actuated separately. Thus, the previous rejections of claims 1 and 18 with respect to Huebsch are sustained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 8, 9, 11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebsch et al. (US 5853422).

Art Unit: 3731

Regarding claim 1, Huebsch teaches an applier for an anastomosis ring device having proximal (14), center (18), and distal rings (16) connected respectively by proximal and distal hinged arms (22), the ring device having a generally cylindrical shape when unactuated (fig. 2) and a rivet shape when actuated (fig. 4), the applier comprising:

an elongate implement portion (40);

a handle connected to the implement portion (300);

an first actuating member (130) internally engaged to a selected one of the rings of the anastomosis device;

an arresting member (124) internally engaged to a selected second of the three rings (116) of the anastomosis device;

a second actuating member (132) internally engaged to the third of the three rings of the anastomosis device;

a first control (310) coupled to the handle operably configured to cause movement of the first actuating member (130), and thus the engaged ring (114), toward the arresting member (128),

a second control (312) coupled to the handle (300) operably configured to cause movement of the second actuating member (132) toward the arresting member (Column 5, proximate lines 55-58); wherein the first and second controls may be selectively positioned to reduce a first longitudinal separation between the center ring and a selected one of the proximal and distal rings causing actuating of the interposed hinged arms of the ring device while maintaining a second longitudinal separation between the

Art Unit: 3731

center ring and the other ring preventing actuating of the interposed hinged arms of the ring device (it is noted that the device of Huebsch is capable of performing this function); and wherein the first and second controls may be selectively positioned to reduce the longitudinal separation between the center ring and both the proximal and distal ring, causing actuation of all of the hinged arms of the ring (it is noted that the device of Huebsch is capable of performing this function).

Regarding Claim 5, Huebsch teaches the applier of claim 1, wherein the arresting (124) member engages the center ring (118), the second actuating member (130) engaged to the proximal ring; and the first actuating member (132) engaged to the distal ring

Regarding Claim 8, Huebsch teaches the applier of claim 1, wherein the selected one of the first and second actuating members (132) and the arresting member that is engaged to the distal ring of the ring device terminates in a catch (inner notch of arresting member 124).

Regarding Claim 9, Huebsch teaches the applier of claim 8, wherein the selected one of the first and second actuating members and the arresting member that is engaged to the distal ring of the ring device include a releasing surface (140) responsive to an actuated condition of the ring device to disengage the actuating member from the selected ring of the ring device (figs. 7 and 8).

Regarding Claim 11, Huebsch teaches the applier of claim 1, wherein the implement portion is dimensionally sized for endoscopic surgical use (fig. 5a).

Art Unit: 3731

Regarding Claim 18, Huebsch teaches an applier for an anastomotic ring device having a center ring (18) longitudinally connected by a plurality of proximal arms (22) to a proximal ring (14) and by a plurality of distal arms (22) to a distal ring (16), the ring expanding each plurality of arms by compressing a respective ring toward the center circular portion, the applier comprising:

a means for inserting an unactuated anastomotic ring device to an anastomotic surgical site (fig. 5a); a means for inwardly compressing proximal and distal rings to actuate both plurality of arms (fig. 4); and a means for actuating a selected one of pluralities of the proximal arms and of distal arms holding the unselected plurality unactuated for positioning tissue lumens for anastomosis and for actuating both pluralities of proximal and distal arms to deploy the anastomosis ring device (Column 5, proximate lines 55-65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 3731

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Adams (US 6632227). Huebsch teaches all elements of preceding dependent claims 1, 8 and 9 as previously described, wherein the applier includes a distal tip illuminator connected to the implement portion. Adams teaches an endoscopic device wherein the distal end comprises a light at the distal end in order to make visual observations of the desired site. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Huebsch with a light at the distal end as taught by Adams in order to make visual observations of the desired site.

Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 12, 13, 15 and 17 allowed. The prior art of record fails to teach wherein the applier comprises a member operative to engage the center ring.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3731

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
11/6/06


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
11/6/06